



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/286,189	08/05/94	SANHUEZA	S MISMS1038348

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330 UNIVERSITY AVENUE
SUITE 701
TORONTO ON M5G 1R7
CANADA

HM12/0621

AIR MAIL

EXAMINER

PARKIN, J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED:

06/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

*Office
dated 6/24/02
to Jallies
(C)*

Office Action Summary

Application No.
08/286,189

Applicant(s)
Sanhueza et al.

Examiner
Jeffrey S. Parkin, Ph.D.

Group Art Unit
1641



☒ Responsive to communication(s) filed on 27 Mar 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 3-9, and 11-16 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 3-9, and 11-16 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 24

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Response to Amendment

Status of the Claims

1. Acknowledgement is hereby made of receipt of the amendment submitted 27 March, 2000. None of the claims were amended in this reply and no new claims introduced. Claims 1, 3-9, and 11-16 are pending in the instant application.

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35 U.S.C. § 112, First Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. Claims 1, 3-9, and 11-16 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As previously set forth, the claims are directed toward RSV vaccine compositions that are capable of inducing non-immunopotentiating and protective immune responses in humans, their methods of preparation, and immunization methods employing said vaccine compositions. Applicants traverse and submit that the cotton rat provides an art-recognized model for studying human immune responses to RSV. In particular, Coe et al. (1996) was presented in support of this assertion. This teaching states in the introduction that recent clinical studies with RSV have shown a "high level of correlation between experimental results in cotton rats and outcomes in clinical trials."

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Contrary to applicants' assertions, the Coe et al. (1996) teaching fails to enable the claimed invention. First, this teaching fails to provide any evidence pertaining to the suitability of the cotton rat model for predicting immune response in humans. Second, while reference was made to other published studies, none of the relevant facts were provided from those studies in this publication. Descriptions of the immunogen employed and immune parameters examined were not provided. Third, the prior art clearly provides a reasonable basis for questioning the validity of the cotton rat model and also epitomizes the difficulties associated with RSV vaccine development. Applicants are advised that the presentation of more appropriate publications or other suitable evidence providing reproducible data derived from the cotton rat model might obviate the rejection. However, in the absence of such data the rejection is hereby maintained.

Finality of Office Action

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A **SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.**

Correspondence

5. The Art Unit location of your application in the Patent and

Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1641**.

5 6. Correspondence related to this application may be submitted to
Group 1600 by facsimile transmission. The faxing of such papers
must conform with the notice published in the Official Gazette,
1096 OG 30 (November 15, 1989). Official communications should be
10 directed toward one of the following Group 1600 fax numbers: (703)
308-4242 or (703) 305-3014. Informal communications may be
submitted directly to the Examiner through the following fax
number: (703) 308-4426. Applicants are encouraged to notify the
Examiner prior to the submission of such documents to facilitate
their expeditious processing and entry.

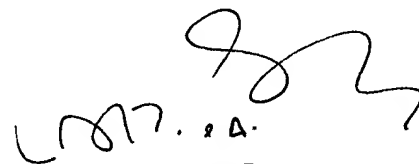
15 7. Any inquiry concerning this communication should be directed to
Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227.
The examiner can normally be reached Monday through Thursday from
8:30 AM to 6:00 PM. A message may be left on the examiner's voice
20 mail service. If attempts to reach the examiner are unsuccessful,
the examiner's supervisors, James Housel or Laurie Scheiner, can be
reached at (703) 308-4027 or (703) 308-1122, respectively. Any
inquiry of a general nature or relating to the status of this
application should be directed to the Group 1600 receptionist whose
25 telephone number is (703) 308-0196.

Respectfully,



Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1641

16 June, 2000



Laurie Scheiner
PRIMARY EXAMINER